DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 23, 2015

Guangzhou Finecure Medical Equipment Co., Ltd
% Field Fu
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
4th Floor, Jinhui Building, Nanhai Blvd,
Nanshan District, Shenzhen, 518000
China

Re: K140265
Trade/Device Name: Electrode for Urinary Incontinence
Regulation Number: 21 CFR 876.5320
Regulation Name: Non-Implanted electrical continence device
Regulatory Class: II
Product Code: KPI, HIR
Dated: December 10, 2014
Received: December 14, 2014

Dear Field Fu,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K140265

Device Name
Electrode for Urinary Incontinence

Indications for Use *(Describe)*
The Urinary Incontinence Probe, model PR-51 Vaginal Probe & PR-52 Anal Probe are intended to provide electromyographic feedback from pelvic musculature or electrical stimulation to pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control during the treatment of urinary incontinence.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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SECTION 05 510(k) Summary

This summary of 510(K) safety and effectiveness information is submitted As Required by requirements of SMDA and 21 CFR §807.92.

1 Administrative Information

Date of Summary prepared	Jan, 19, 2014
Manufacturer information	Company title: Guangzhou Finecure Medical Equipment Co., Ltd. Company address: F19, No.1 Kesheng Road, Baiyun Torch Building, No.1633 Beitai Road, Baiyun District, Guangzhou, CHINA Phone: +86(020) 2802 6079 Fax: +86(020) 2802 6059 Contact Person: Chiping Ma E-mail: Finecure_export@163.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. 4th Floor, Jinhui Building, Nanhai BLVD, Nanshan District, Shenzhen, Guangdong, China. Contact person: Mr. Field.Fu E-Mail: cefda13485@163.com QQ：670312758 Website: www.cefda.com
Establishment registration number	No.

2 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Electrode for Urinary Incontinence
Model:	PR-51, PR-52

Classification name:	Stimulator, electrical, non-implantable, for incontinence; Perineometer.
Review Panel:	Gastroenterology/Urology; Obstetrics/Gynecology.
Product Code:	KPI; HIR
Device Class:	II
Regulation Number:	876.5320;884.1425

3 Predicate Device Information

Sponsor:	VERYWAY MEDICAL INSTRUMENT CO., LTD
Device:	Everyway Incontinence Stimulation Electrode Model: PR-02/02A, PR-03103A, PR-04104A, PR-10A, PR-h1A, PR-14A for Life-Care VaginalProbe & PR-06/06A, PR-1 2A, PR-1 3/13A for Life-Care Anal Probe.
510(K) Number:	K122194

4 Device Description

The Urinary Incontinence Probe, model PR-51 Vaginal Probe & PR-52 Anal Probe are the light weight cylinder consisting of two independent conductive rings that are paired and isolated, physically and electrically. The cylinder is shaped with a handle for comfort positioning in vaginal/anal canal for incontinent treatment as above mentioned and easy for removing after treatment. It is watertight to allow for washing with soap and water between uses. The probe is designed for repeated intermittent use in home or clinic for up to one year by a single user. It does not require sterilization, but does required washing for reuse according to the validated cleaning method as recommended in user manual.

To fit with different type of device connection, the lead wire of device was provided with three different type of wire connection terminals, 2mm pigtail, 3.5mm femelle and 2.35 mm femelle. Either of the PR-51 Vaginal Probe & PR-52 Anal Probe can be connected to any one of three connection terminals.

5 Intended Use

The Urinary Incontinence Probe, model PR-51 Vaginal Probe & PR-52 Anal Probe are intended to provide electromyographic feedback from pelvic musculature or electrical stimulation to pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control during the treatment of urinary incontinence.

6 Indication for Use

The Urinary Incontinence Probe, model PR-51 Vaginal Probe & PR-52 Anal Probe are intended to provide electromyographic feedback from pelvic musculature or electrical stimulation to pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control during the treatment of urinary incontinence.

7 Technological characteristics of the proposed device compared to the predicate device

The proposed device and the Predicate device have the same intended use, design principle, and similar material composition. The differences do not exert adverse effect on the proposed device. The proposed device is substantially equivalent to the predicate devices.

8 Brief discussion of the nonclinical tests

Electrode for Urinary Incontinence conforms to the following standards:

- ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process;
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity;
- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.

9 Brief discussion of clinical tests

Not applicable.

10 Other information (such as required by FDA guidance)

No other information.

11 Conclusions

The subject device---Electrode for Urinary Incontinence PR-51, PR-52 are substantially equivalent to Everyway Incontinence Stimulation Electrode whose 510(k) number is K122194.